

We are committed to—

STRENGTHENING IMMUNIZATION SCIENCE AND COMMUNICATING THE RESULTS

*T*he National Immunization Program (NIP) undertakes and promotes a wide range of scientific activities, including tracking and monitoring disease, disease outbreak investigations, evaluations of health care delivery methods and systems, and social and behavioral science research. Importantly, NIP works to translate research findings into actions and recommendations and to communicate these to the right audiences.

VACCINE PROTECTION EXPANDED

Today, the childhood immunization schedule recommends that all children in the United States be protected against 11 vaccine-preventable diseases. This ability to protect children and adults from vaccine-preventable diseases stems directly from CDC's commitment to disease prevention. Strengthening immunization science and communicating the results are key components in NIP's efforts to expand vaccine protection.

The National Immunization Program conducts research with a number of partners, including research universities and health departments, to develop and evaluate immunization recommendations and programs. Epidemiologists, physicians, and scientists from NIP are involved in clinical trials, disease surveillance studies, disease outbreak investigations, and studies designed to improve the safety, effectiveness, and delivery of vaccines.

Importantly, NIP disseminates new immunization recommendations and relevant findings from research or field experience as quickly as possible so public health officials, health care providers, and others can act upon the information. Up-to-date information and resources are posted on NIP's web site, and links are provided to a number of other related sites.

Major Events of the Past Year in Vaccine Protection

CHILDHOOD VACCINE-PREVENTABLE DISEASES REDUCED

Polio

Polio caused by the wild polio virus no longer occurs in the U.S. The last case of wild-virus polio, indigenously acquired in the U.S., occurred in 1979, and the last indigenous case in Western Hemisphere occurred in 1991. The goal remains to achieve global eradication of the disease by 2005.

Measles

Measles virus, once the cause of a routine childhood illness, is no longer circulating in the United States. Only 37 cases (provisional data) were reported in the U.S. in 2002. All of those cases were either directly linked to international importations or believed to be linked to such importations.

Rubella

Rubella cases have declined from 57,600 in 1969, when the vaccine was first available, to a total of 12 cases in 2002 (provisional data), and congenital rubella syndrome (CRS) cases have dropped by 99 percent during the same period. In recent years, rubella cases have mainly occurred among foreign-born adults from countries that have either not established, or have just established, national rubella vaccination programs. There were no reports to the CDC National Congenital Rubella Syndrome Registry of children being born with CRS in 2002 (provisional data). However, some children born in 2002 may not be diagnosed with CRS until 2003 or later.

Haemophilus influenzae type b

Haemophilus influenzae type b (Hib) is no longer the leading cause of meningitis among children younger than 5 years old in the United States. This disease was once responsible for 20,000 serious infections among young children each year. However, since 1993 the widespread use of the Hib vaccine has reduced the incidence of Hib invasive disease in children younger than 5 years of age by more than 99 percent.

APPLIED RESEARCH AND DEVELOPMENT

Needle-Free Injection Technology

Efforts are being pursued to overcome the drawbacks and limitations of vaccination with conventional needle and syringe. Through Small Business Innovation Research contracts, a new generation of safe, needle-free, high-speed jet injector immunization devices is being developed. These devices could be used for rapid protection of a population against vaccine-preventable diseases (such as mass campaigns to eradicate measles), control of epidemics of meningococcal disease and pandemics of high-mortality influenza, and to help respond to some forms of bioterrorism.

Additional activities include participation in conferences and international standards development for jet injection, setting priorities for research and development funding for new vaccine administration technologies on behalf of the Global Alliance for Vaccines and Immunization and the World Health Organization, and maintenance of a comprehensive Web site and news service on needle-free administration of drugs.

Aerosol Vaccination Device

Aerosol vaccination has been shown to be an effective way to deliver measles vaccine; however, the equipment used is cumbersome and has many technical limitations. An aerosol vaccination device which overcomes the previous limitations and is designed for mass measles vaccination has been developed by NIP. Device development and testing is in progress through a Small Business Innovation Research contract, and CDC has applied for a patent. Laboratory tests show the handheld battery-powered prototypes deliver live measles vaccine aerosols without loss of potency. Research-in-progress will test the device in animal studies to confirm the safety and immunogenicity of measles vaccine delivered by the device. Phase I trials in humans are planned to begin in 2003.

Intranasal Influenza Vaccine for Children

Evaluations are being conducted on the safety and efficacy of the live, attenuated, intranasally-administered influenza vaccine for children. These evaluations will help guide policy development for use of this vaccine in children once it is licensed.

Potential for Use of Pneumococcal Conjugate Vaccine in the Elderly

The only pneumococcal vaccine currently licensed for use with adults is the pneumococcal polysaccharide vaccine (PPV), which provides somewhat limited protection for the elderly. The National Immunization Program and Emory University are planning to conduct a clinical trial to determine if protection can be increased by using a combination of PPV and the new pneumococcal conjugate vaccine (PCV). This trial will assess the effectiveness of administering a combination of PPV and PCV given with and without a priming dose of tetanus vaccine. If a combination of vaccines is

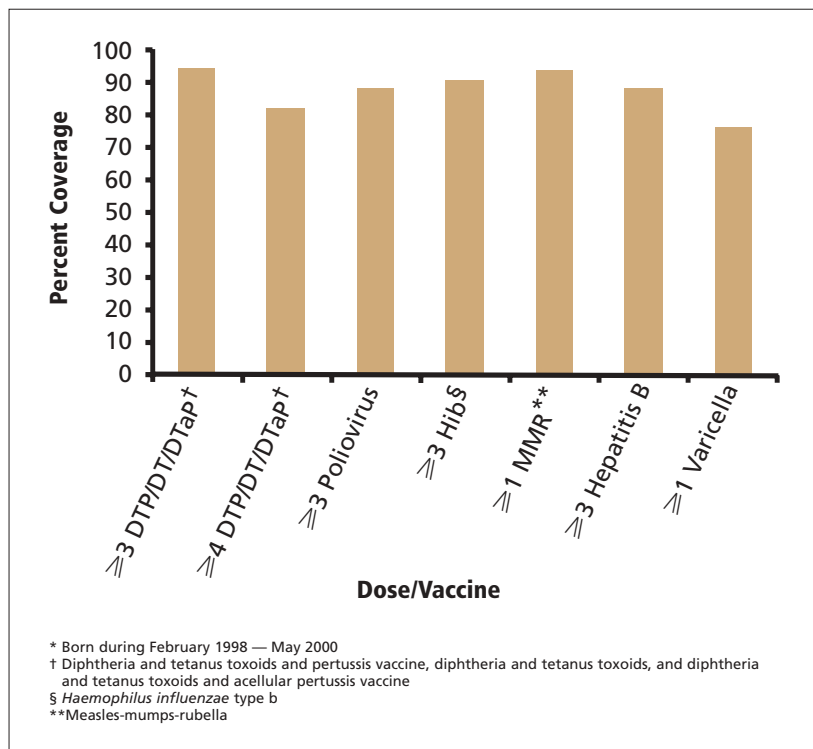
more effective than using PPV alone, studies will be performed to measure how much better this protects the elderly from pneumonia.

Annual Conference on Vaccine Research: Basic Science—Product Development—Clinical and Field Studies

The Centers for Disease Control and Prevention is a co-sponsor of this conference. Begun in 1998, this conference has become the largest scientific meeting devoted exclusively to the research and development of vaccines and associated technologies for disease control through immunization.

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Vaccination Coverage Levels Among Children Aged 19–35 Months, by Selected Vaccines, National Immunization Survey, United States, 2001*



SURVEILLANCE AND EVALUATION

National Immunization Survey

The National Immunization Survey (NIS) is the nation's primary tool for assessing immunization coverage among preschool-aged children in the U.S. This random-digit-dial telephone survey is conducted annually by the CDC to obtain national, state, and selected urban-area estimates of vaccination coverage rates for U.S. children aged 19 to 35 months. Vaccination information obtained from the telephone survey is then validated by surveys that are mailed to the children's vaccination providers.

In addition to providing estimates of immunization coverage, the NIS provides other insights into immunization. For example, data from the NIS have recently been used to examine the timeliness of vaccine administration among infants and preschool-aged children in the United States. This study found that nine out of every 10 children surveyed had received one or more vaccinations outside of the Advisory Committee on Immunization Practice's (ACIP) recommended age ranges for the vaccines. These findings point out the need for closer adherence to the recommended childhood immunization schedule so that children do not have periods of time when they are under-vaccinated and thus are at increased risk for disease.

The NIS revealed that, in 2001, coverage with three or more doses of any diphtheria and tetanus toxoids and pertussis vaccine (DTP/DTaP/DT) was 94.3 percent; coverage with three or more doses of any poliovirus vaccine was 89.4 percent; coverage with one or more doses of measles-mumps-

rubella vaccine (MMR) was 91.4 percent; coverage with three or more doses of Hib vaccine was 93.0 percent; and coverage with three or more doses of hepatitis B vaccine was 88.9 percent. Furthermore, coverage with one or more doses of varicella vaccine at or after the child's first birthday (unadjusted for history of varicella illness) increased from 67.8 percent in 2000 to 76.3 percent in 2001. Overall, coverage for the vaccines routinely recommended for childhood immunizations were at or near record levels, which accounts for the record or near record low number of vaccine-preventable diseases. Estimates of vaccination coverage for children aged 19 to 35 months in 2001 are available on the NIP web site at www.cdc.gov/nip/coverage

New Vaccine Surveillance Network

The New Vaccine Surveillance Network was established in 1999 to study the impact of new and prospective vaccines and new vaccine policies. Current surveillance sites are based in Rochester, New York; Nashville, Tennessee; and Cincinnati, Ohio. Site investigators have established year-round population-based inpatient surveillance of acute respiratory infections in children younger than 5 years of age residing in nine counties who have been admitted to study area hospitals. Other network projects include surveillance for acute respiratory infections among outpatients in community practices and hospital emergency departments, assessment of risk factors for severe influenza and respiratory syncytial virus infections illness, evaluation of the feasibility of universal influenza recommendations in young children,

assessment of pneumococcal conjugate vaccine administration by providers and its impact on the childhood vaccination schedule, and analysis of the impact of pneumococcal conjugate vaccination on disease outcomes.

Provider-Based Assessment Tools

Clinic Assessment Software Application has been developed to allow immunization providers to identify adult and adolescent patients who have a higher risk of getting a vaccine-preventable disease or suffering complications from such a disease. This software will also help health care providers determine how many adults have received the influenza and pneumococcal vaccines as well as other vaccines recommended for the adult population. The software was tested in several states including California and Oregon during 2001 and 2002. The first version was distributed at the National Immunization Conference in April of 2002 and is currently available to all state and local immunization programs and providers.

Improved Influenza and Pneumococcal Vaccination among Seniors in Nursing Homes

In collaboration with their Quality Improvement Organizations, the Centers for Medicare and Medicaid Services and CDC recently completed a 3-year program to promote standing orders for Medicare patients in nursing homes. Baseline data showed that standing orders are both more effective and more cost-effective than other types of immunization programs in nursing homes. Changes in the level of implementation and coverage for influenza and pneumococcal vaccinations are being evaluated.



Current and Future Activities in Vaccine Protection

Many new and innovative developments are on the horizon for preventing disease through immunization. For example, a new vaccine combining DTaP, hepatitis B, and inactivated poliovirus vaccine was licensed by the Food and Drug Association (FDA) in 2002. This vaccine is already being supplied to the private sector under the name PEDIARIX. The ACIP will consider a formal recommendation for adding this vaccine to the routine immunization schedule and a resolution for coverage by the Vaccines for Children program in 2003. In the next few years, a new vaccine for preventing meningococcal disease in infants, an intranasal influenza vaccine for both children and adults, and a combination measles-mumps-rubella-varicella vaccine may also be licensed. Taking these new vaccines from development all the way to routine use requires a multifaceted approach encompassing the following components.

- ▶ Enhanced surveillance to define disease burden and to monitor vaccine safety and effectiveness
- ▶ Enhanced assessment of public and health care provider attitudes and behaviors to identify potential barriers to successful vaccine introduction, such as beliefs that a particular disease is not potentially serious or that vaccine adverse effects are potentially more dangerous than the disease.
- ▶ Enhanced collaboration with other federal agencies such as the National Institutes of Health and the FDA.
- ▶ Collection and analysis of new data on vaccine economics and cost-effectiveness as new, more expensive vaccines and combination vaccines are introduced.
- ▶ Collaboration with international partners to promote introduction of new vaccines in the developing world.



Success Story

EXPANDING VACCINE PROTECTION

Rubella and Congenital Rubella Syndrome Near Elimination in U.S

The United States has established a goal for eliminating indigenous rubella and congenital rubella syndrome (CRS) by 2010. The number of reported cases of rubella has dramatically declined from 57,600 when the vaccine was introduced in 1969: only 12 cases of rubella were reported and there were no reports of children born with CRS in 2002 (provisional data). However, some children born in 2002 may not be diagnosed with CRS until 2003 or later. Most of the rubella cases occurred among foreign-born adults. This decline is expected to continue as a result of strong vaccination programs and the continued progress with molecular typing. This research will help identify the source and spread of rubella outbreaks and CRS cases in the U.S. and will help determine the rubella strain variations in the U.S.